Catherine Bernard, Ph.D.

Senior Regulatory Affairs Consultant

Core Competencies

- Author US, EU and ROW
- Vaccines and Biologics
- Combo Devices
- Small Molecule
- Briefing Books
- Orphan Designated Products
- FDA Modules 1,2,3,4,& 5
- Clinical Protocols
- 505(b)(2) Pathway

Professional Summary

Dr. Bernard directs our regulatory efforts and is a key strategist working closely with our client's submission team. At DSI, Catherine oversees the regulatory aspects of small and large molecule products as well as innovative drug delivery systems including the coordination of chemistry, manufacturing and controls (CMC) information into regulatory filings. She has more than 25 years of experience in the pharmaceutical industry, with an extensive background in defining regulatory strategies to achieve corporate goals and moving early stage drug development programs to global regulatory submission and commercial launch. Dr. Bernard is a subject matter expert for submission life cycle management, including both large and small molecule in all dose formulations.

- More than fifteen years of industry experience in vaccines, pharmaceuticals, biotechnology, and combination device products,
- Expertise in regulatory affairs and regulatory compliance to meet US and European standards,
- Experience in regulatory strategy for drug development.

Before joining DSI, Catherine held the position of vice president of research and process development at Valorum. She holds a Ph.D. in Biochemistry and Cell Biology from Université Paul Sabatier Toulouse III. She leads the CRO's FDA and EMEA filing strategies in the UK.

On behalf of our clients, Dr. Bernard has successfully negotiated with agencies, submitting briefing books and in-person meeting attendance. She is well versed in the many aspects of authoring in the electronic CTD format. In her time in industry, Catherine has supported multiple dosage forms at various stages of development.

Education

Ph.D.	Option Cell Biology & Biochemistry	Université Paul Sabatier
M.S.	NeuroSciences & Behavioral Studies	Université Paul Sabatier

Professional Experience

Pre-IND meeting and IND submission

- Write and prepare the letter and the list of questions to request a pre-IND meeting with the FDA,
- Write and prepare pre-IND Package,
- Attend pre-IND meeting as a chairman, coordinator or scribe depending on the need from the Sponsor,
- Write and prepare the IND in an eCTD format (modules 1, 2, 3, 4 and 5),
- Submit IND electronically,
- Maintenance of IND as amendment and annual report.

Product and therapeutic area

- Two (2) HIV viral vector vaccine with the Division of Vaccines and Related Products Applications,
- One (1) rotavirus ex-US development,
- One (1) antibacterial vaccine,
- Several (7) stem cell products with the Office of Cellular, Tissue and Gene Therapies,
- Three (3) investigational products with the Division of Cardiovascular and Renal Products,
- Three (3) investigational products with the Division of Dermatology and Dental Products including one dermatological/cancer investigational product,
- One (1) investigational products with the Division of Gastroenterology and Inborn Errors Products,
- Two (2) investigational products (one biosimilar and one small molecule) with the Division of Pulmonary, Allergy and Rheumatology Products,
- One (1) investigational products with the Division of Bone, Reproductive and Urologic Products,
- One (1) for a biosimilar to Humira,
- Two (2) combination product for neuro/oncology products.

Pre-NDA meeting and information package submission

- Write and prepare a package, cover letter and the list of questions to request a pre-NDA meeting:
  - FDA Division of Anesthesia, Analgesia, and Addiction Products,
  - FDA Division of Division of Gastroenterology and Inborn Errors Products,
  - FDA Division of Pulmonary, Allergy and Rheumatology Products.

Orphan designation Application

- Write and prepare the orphan designation application,
- Write and prepare orphan grant application.

Product and therapeutic area

- One HIV viral vector vaccine,
- One stem cell product,
- Two (2) cardiovascular investigational product,
- One dermatological investigational product,
- One small molecule GI tract,
- One for DMD indication,
- One for ALS indication,
- One for combination product for oncology product,
- Two (2) for pancreatic cancer,
- One for narcolepsy.

Clinical Investigator's brochure

- Write and prepare/update IB from nonclinical and clinical study reports.

Product and therapeutic area

- One HIV viral vector vaccine,
- One Rotavirus Vaccine,
- One stem cell product,
- Two dermatological investigational products,
- One dermatological/cancer investigational product.

Clinical protocol

- Write and prepare a draft clinical protocol to be edited by the principal investigator.

Product and therapeutic area

- One dermatological investigational product,
- One Rotavirus product.

BLA, NDA and ANDA submission

- Write and Prepare two NDA 505(b)(2) pathway for opioid product and injectable product,
- Write and prepare NDA 505(b)(2) pathway (Module 3 and Module 2 QOS) for a combination product (pump and product),
- Write and prepare a BLA modules 2 and 3 for a blood product,
- Write and prepare a BLA modules 2 and 3 for a stem cell product,
- Write and prepare Module 3 for a BLA application from batch records and SOPs and Module 2 for two conjugate vaccines, submission through mutual recognition and centralized procedure in Europe and US and follow-up,
- Write and preparation Modules 2, 3 and 4 of a CTD for an Hepatitis B vaccine,
- Write and prepare Module 3 and Module 2 for a 505(b)(2) NDA for a opioid product,
- Write and prepare 505(b)(2) NDA modules 1, 2, 3, 4 and 5 for a combination device-drug (reformulation of an existing product) – and submit electronically,
- Prepare four (4) 505(b)(j) ANDA modules 1, 2, 3 and 5 and submit electronically,
- Preparation of 8 DMFs for conjugate vaccine products and silver API.

BLA, NDA and ANDA Post Approval submission/CRL Responses

- Assist in the preparation of 3 Complete Response Letters (CRL) ,
- Use several amendments to update a BLA NDA modules 2 and 3 for several vaccine products (Flu-type),
- Convert and update Module 2 and Module 3 for 4 antibiotic products,
- Convert a Pre-Approval Supplement into a Type 2 Variation for European submission for a vaccine product.

DMF submission

- Review and submit electronically 5 DMF for a European API facility,
- Review and submit electronically 3 DMF for an Argentinian API facility,
- Assist in FDA inspection,
- Prepare and submit electronically Drug Establishment Registration and Self Identification,
- Maintenance of all DMFs.

Electronic Submission

- All IND and NDA/BLA were prepared for electronic submission,
- Lorentz Software for publishing,
- Submission via the FDA Gateway Portal.

Regulatory Compliance

- Evaluation of the process validation for a monoclonal antibody with emphasis on leachables and extractables,
- Preparation of SOPs, Batch Records and technology transfer to GMP manufacturer for a viral vaccine delivery system,
- Audits of research laboratories (GLP oriented) for IND purposes and preparation of manufacturing plant (GMP oriented) for FDA pre-approval inspection,
- Review all CAPA for all vaccine products for a Big Pharma.

Work Experience

Design Space Inpharmatics, LLC **2010-Present**
Senior Regulatory Consultant

International Regulatory Affairs Services, Inc. **2000-Present**
President, Regulatory Affairs

Wyeth **1998-2000**
Regulatory Affairs Associate

Valorum, Inc. **1996-1998**
Senior Regulatory Affairs Executive

European Regulatory Affairs **1995-1996**
Regulatory Affairs Consultant

Applied Microbiology, Inc **1994-1995**
Project Manager Assistant

Regeneron, Inc **1992-1994**
Post-Doctoral Scientist